



Primary prevention of CVD to high risk PAD patients, a Sprectrum of Risk: role of lipid lowering and antiplatelet therapy

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Dr. Beth Abramson

Primary Prevention of CVD to High-Risk Patients: Role of lipid lowering and antiplatelet therapy

Relationships with financial sponsors:

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- **Patents:** N/A
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Overall learning objectives

Participants should be able to:

1. Review lipid lowering and risk enhancers in primary prevention
2. Review lipid lowering in higher risk PAD patients
3. Review the role of ASA in primary prevention
4. Review evidence based medical therapy for antithrombotic therapy in PAD



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Polling Question 1:

- In a 65 year old with DM, MI 18 month ago, with EGFR of 49, optimal anticoagulation is:
- EC ASA 81
- DAPT
- EC ASA 81 + Rivaroxiban 2.5 BID
- EC ASA 81 + Rivaroxiban 5 BID
- None of the above



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Polling Question 2:

- In a 49 year old with PAD optimal anticoagulation is:
- EC ASA 81
- DAPT
- EC ASA 81 + Rivaroxiban 2.5 BID
- EC ASA 81 + Rivaroxiban 5 BID
- None of the above



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Update on Cardiac Prevention trials 2004 - “Being aggressive outside of the Cath Lab”

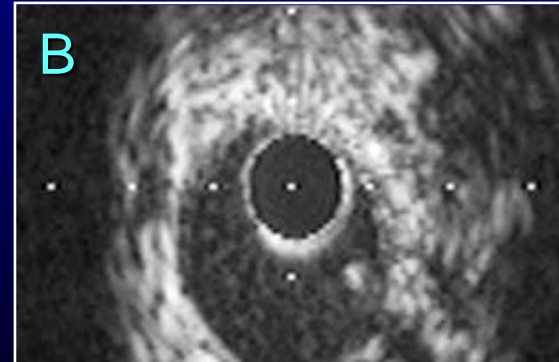
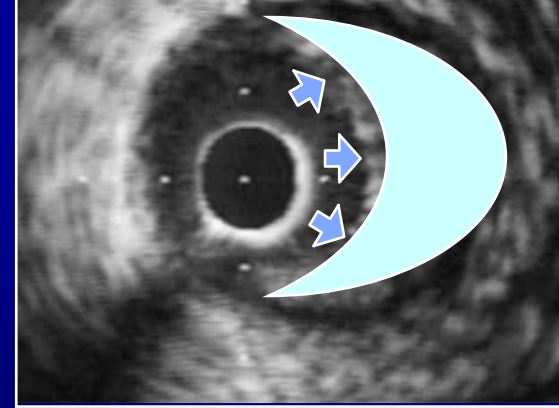
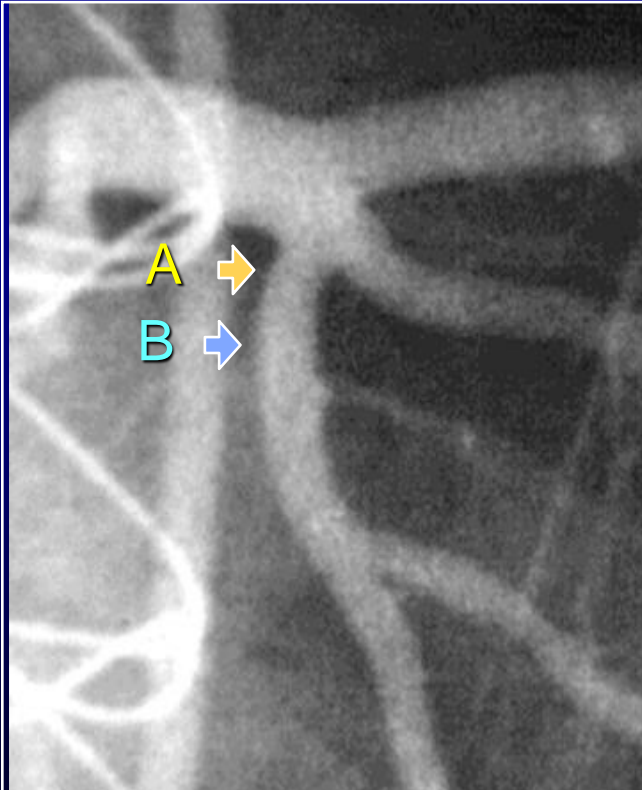
Beth L. Abramson, MD, FRCPC FACC

**Director: Cardiac Prevention & Rehabilitation Centre & Women's
Cardiovascular Health**

St. Michael's Hospital, Division of Cardiology

Assistant Professor of Medicine, University of Toronto

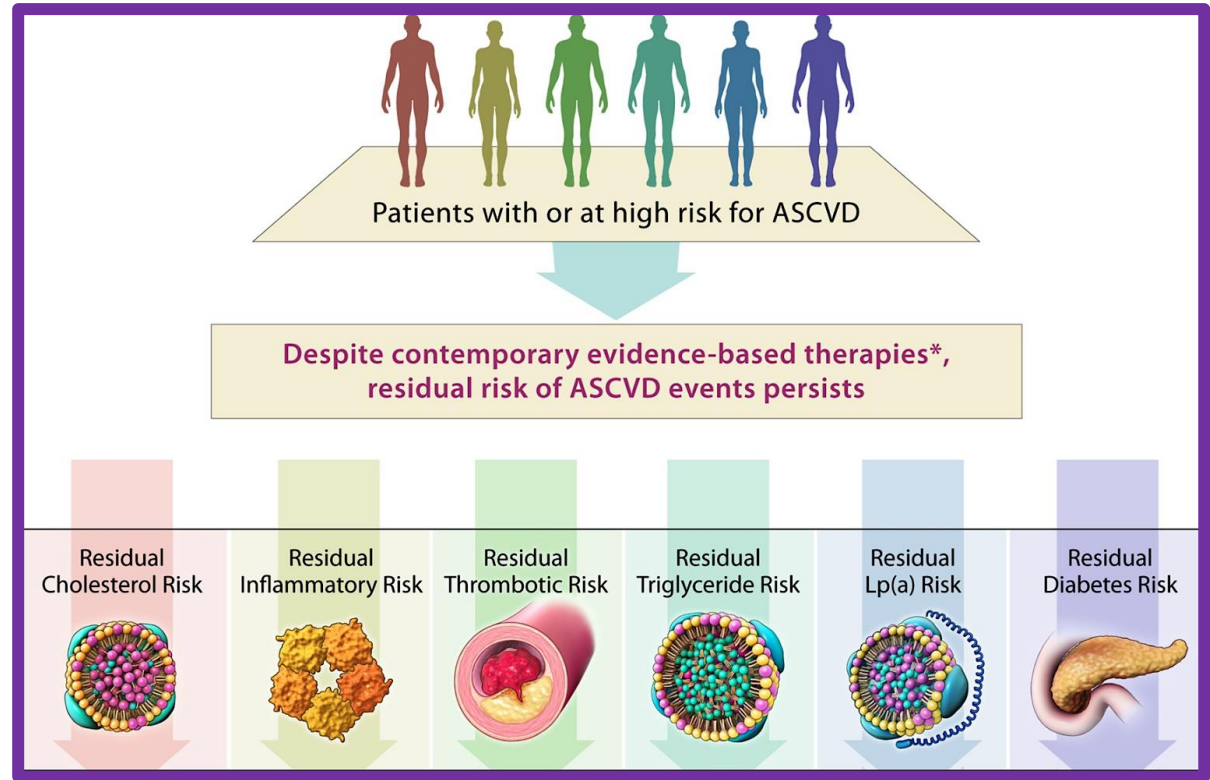
2004: Paradigm Shift



Atherosclerosis is a
DIFFUSE ARTERIAL PROCESS



RESIDUAL RISK PATHWAYS IN SECONDARY PREVENTION



Current concepts of residual risk

Treatment Approach for Primary Prevention Patients (Without a Statin Indicated Condition)‡

Primary Prevention†

Low-Risk*

Statin therapy not recommended for most low risk individuals; exceptions include:
(a) LDL-C ≥ 5.0 mmol/L (or ApoB ≥ 1.45 g/L or non-HDL-C ≥ 5.8 mmol/L) – see Figure 2; or (b) FRS is 5%-9.9% with LDL-C ≥ 3.5 mmol/L (or non-HDL-C ≥ 4.2 mmol/L or ApoB ≥ 1.05 g/L), particularly with other CV risk modifiers (e.g., FHx, Lp(a) ≥ 50 mg/dL [or ≥ 100 nmol/L] or CAC > 0 AU) as the proportional benefit from statin therapy may be similar to other treated groups.

Health Behavior Modifications:

- Smoking cessation
- Diet: it is recommended all individuals adopt a healthy dietary pattern
- Exercise: it is recommended adults accumulate at least 150 mins/week of moderate-vigorous intensity aerobic physical activity

Intermediate Risk*

FRS 10-19.9% and

- LDL-C ≥ 3.5 mmol/L or
- Non-HDL-C ≥ 4.2 mmol/L or
- ApoB ≥ 1.05 g/L or
- Men ≥ 50 years and women ≥ 60 years with one additional risk factor: low HDL-C, IFG, high waist circumference, smoker or HTN **OR** with presence of other risk modifiers: hsCRP ≥ 2.0 mg/L, CAC > 0 AU, family history of premature CAD, Lp(a) ≥ 50 mg/dL (100 nmol/L)

High-Risk*

FRS $\geq 20\%$

Discuss Health Behavior Modifications

Initiate Statin Treatment

If LDL > 2.0 mmol/L or ApoB > 0.8 g/L or non-HDL-C > 2.6 mmol/L on maximally tolerated statin dose

YES

YES

Discuss add-on therapy with patient:

Evaluate reduction in CVD risk vs. cost/access and side-effects

Add-on ezetimibe 1st line
(BAS as alternative)¶

YES

MONITOR: response to statin Rx, response to add-on lipid-lowering Rx, health behavior modifications

‡Statin indicated conditions consists of all documented ASCVD conditions, as well as other high-risk primary prevention conditions in the absence of ASCVD, such as most patients with diabetes, those with chronic kidney disease and those with LDL-C ≥ 5.0 mmol/L.
†Calculate risk using the Framingham Risk Score (FRS) – refer to the iCCS available on the App Store or on Google Play. *Screening should be repeated every 5 years for men and women aged 40 to 75 years using the modified FRS or CLEM to guide therapy to reduce major CV events. A risk assessment might also be completed whenever a patient's expected risk status changes. ¶Studies have evaluated the efficacy of BAS for the prevention of ASCVD, but results have been inconclusive.
FRS, Framingham Risk Score; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; ApoB, apolipoprotein B; IFG, impaired fasting glucose; HTN, hypertension; hsCRP, high-sensitivity C-reactive protein; CAC, coronary artery calcium; AU, Agatston unit; Rx, prescription; BAS, bile acid sequestrant. From: <https://doi.org/10.1016/j.cjca.2021.03.016>, Pearson et al. 2021 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease.

Low-Risk*
FRS <10%

Statin therapy not recommended for most low risk individuals; exceptions include:

(a) LDL-C ≥ 5.0 mmol/L (or ApoB ≥ 1.45 g/L or non-HDL-C ≥ 5.8 mmol/L) – see *Figure 2*; or (b) FRS is 5%-9.9% with LDL-C ≥ 3.5 mmol/L (or non-HDL-C ≥ 4.2 mmol/L or ApoB ≥ 1.05 g/L), particularly with other CV risk modifiers (e.g., FHx, Lp(a) ≥ 50 mg/dL [or ≥ 100 nmol/L] or CAC >0 AU) as the proportional benefit from statin therapy may be similar to other treated groups.

Statin Indicated Conditions:

- LDL ≥ 5
- Framingham 5-9.9%:
- LDL ≥ 3.5 (non HDL ≥ 4.2 or Apo B ≥ 1.05)
- Lp(a) > 100 nmol/L
- CAC > 0



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2021 CCS Recommendations for Lp(a) as a Biomarker for Improving Risk Stratification and Dyslipidemia Management

Measuring Lp(a) level **ONCE** in a person's lifetime as a part of the initial lipid screening is recommended

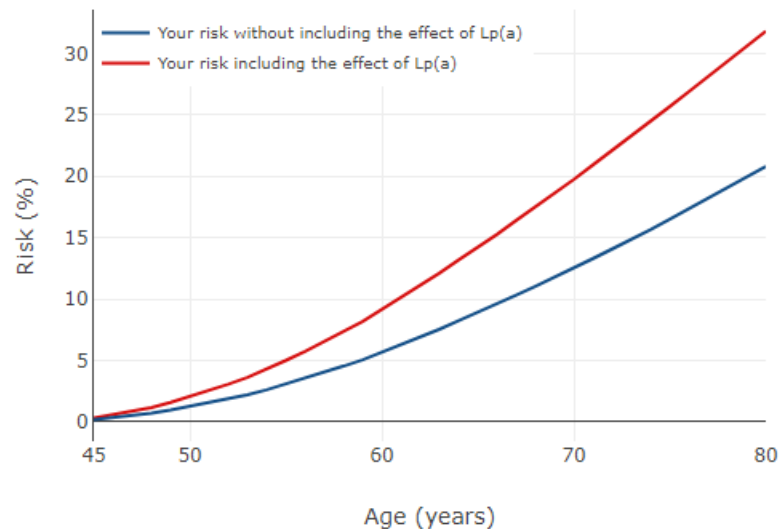
(Strong Recommendation; High Quality Evidence)

For all patients in the setting of **primary prevention** with an **Lp(a) ≥ 50 mg/dL (or ≥ 100 nmol/L)**, earlier and more intensive health behaviour modification counselling and management of other ASCVD risk factors is recommended

(Strong recommendation; Expert consensus)

<https://www.lpaclinicalguidance.com/>

Your risk of having a heart attack or stroke



Your risk of having a heart attack or stroke up to age 80 is:

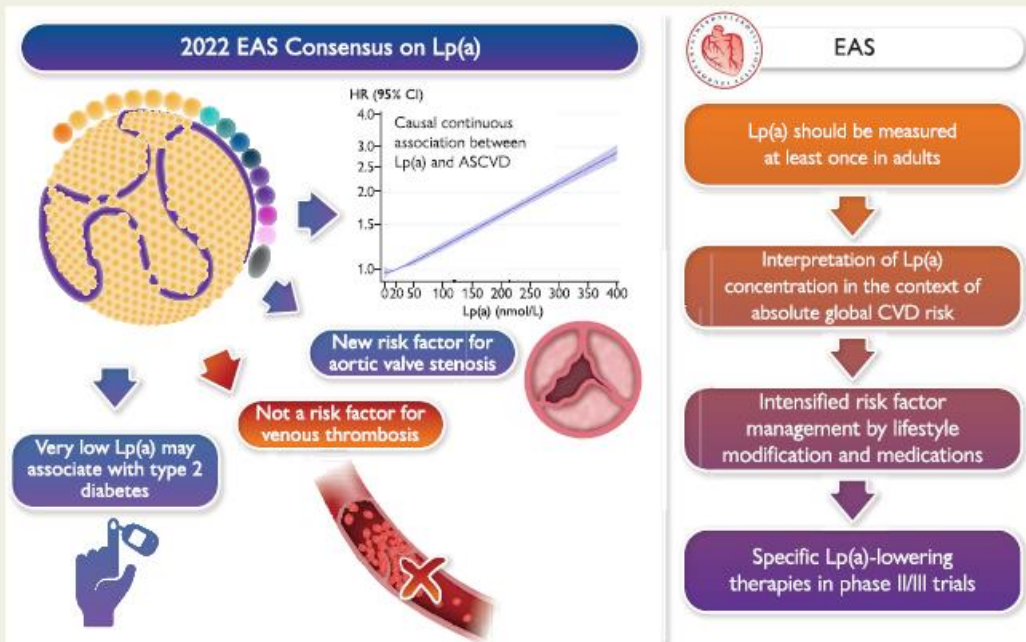
20.8%

With an Lp(a) level of 180 nmol/L, your estimated risk of having a heart attack or stroke up to age 80 changes from 20.8% to:

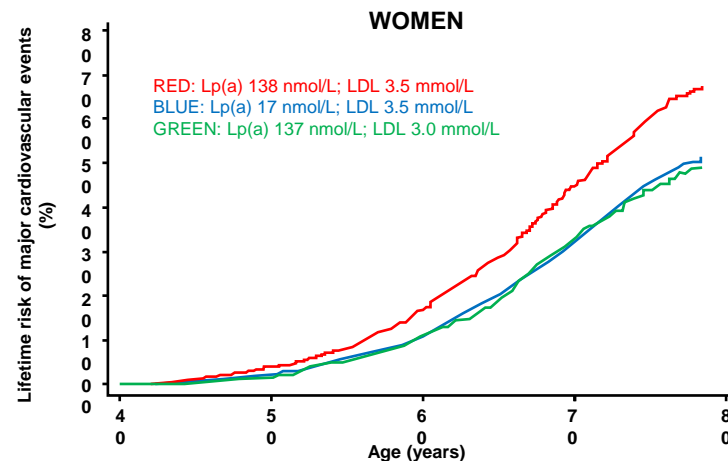
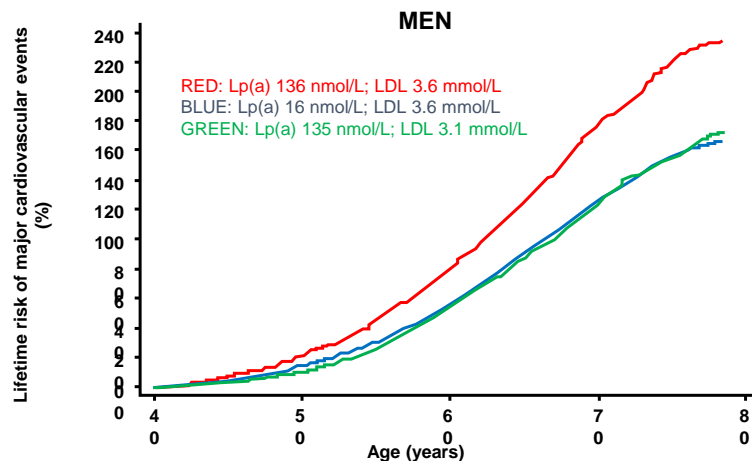
31.8%

Lipoprotein(a) in atherosclerotic cardiovascular disease and aortic stenosis: a European Atherosclerosis Society consensus statement

Graphical Abstract



Lifetime risk of major cardiovascular events with higher lifetime exposure to Lp(a) and lower lifetime exposure to LDL-C



Intensification of LDL-C reduction needed to reduce the global cardiovascular risk to a similar extent as the risk attributable to elevated Lp(a) depending on age at which LDL-C reduction is initiated

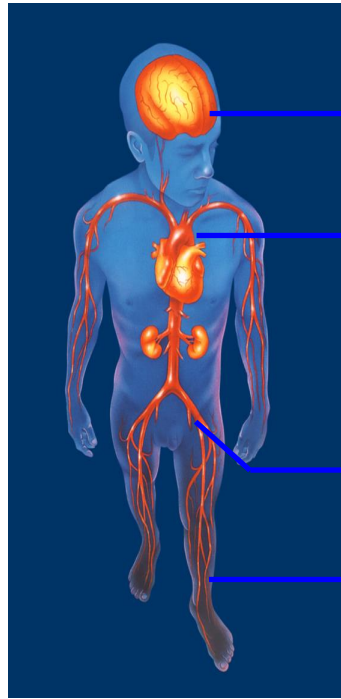
Intensification of LDL-C reduction (nmol/L) needed to mitigate the increased risk caused by Lp(a)

Lp(a) nmol/L	Δ Lp(a) compared to median	Lp(a) percentile	HR for MCVE due to increased Lp(a)	Begin age 30y	Begin age 40y	Begin age 50y	Begin age 60y
320	300	99	2.56	1.2 mmol/L	1.4 mmol/L	1.7 mmol/L	2.3 mmol/L
270	250	97.5	2.19	1.0 mmol/L	1.2 mmol/L	1.5 mmol/L	1.9 mmol/L
220	200	93.5	1.87	0.8 mmol/L	0.9 mmol/L	1.2 mmol/L	1.5 mmol/L
170	150	90	1.60	0.6 mmol/L	0.7 mmol/L	0.9 mmol/L	1.1 mmol/L
120	100	82.5	1.37	0.4 mmol/L	0.5 mmol/L	0.6 mmol/L	0.8 mmol/L
70	50	75	1.17	0.2 mmol/L	0.2 mmol/L	0.3 mmol/L	0.4 mmol/L
20	ref.	50	ref.	ref.	ref.	ref.	ref.

New Areas of Focus in Primary Prevention

- 1 Preventive care of women with hypertensive disorders of pregnancy
- 2 Importance of lipoprotein measurement, including non-HDL-C, ApoB and lipoprotein(a), in assessing CV risk
- 3 Role of coronary artery calcium as a clinical decision-making tool for determining the need to initiate statins
- 4 CV benefit of icosapent ethyl in patients with TGs ≥ 1.5 -5.6 mmol/L and a prior CV event or with diabetes and additional RFs
- 5 Lack of CV benefit of omega-3 fatty acids from dietary sources or other formulations/supplements

Atherosclerosis is a systemic disease that can affect multiple arterial beds



Cerebrovascular disease

Coronary artery disease

Peripheral arterial disease

- Intermittent claudication
- Critical limb ischemia



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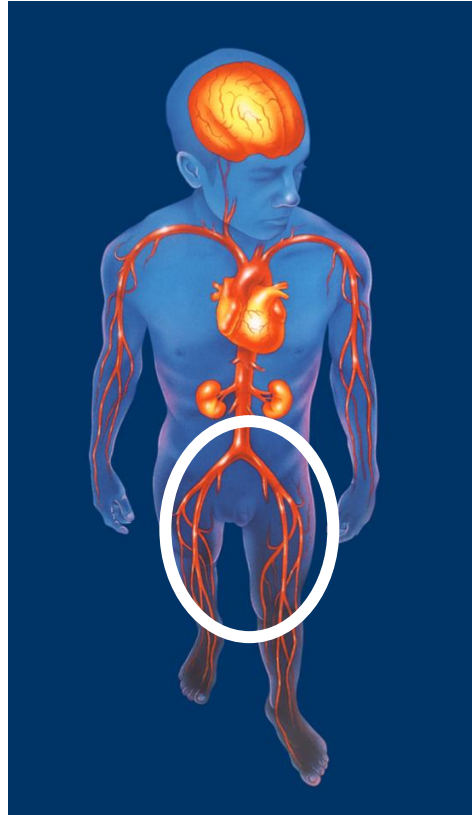
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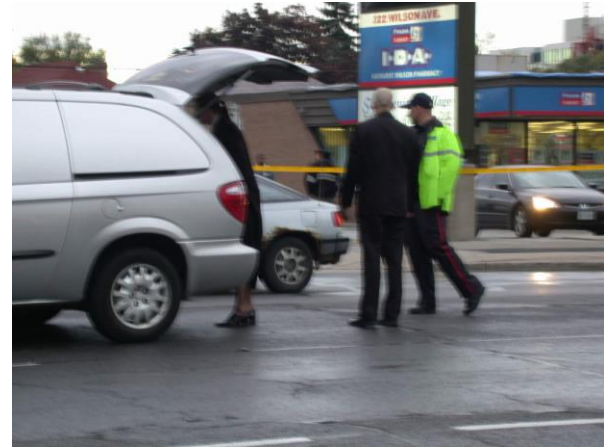
In the Fast Paced World of Cardiology...



PAD is the Poor Cousin!



But it's Just as Deadly!



CCS 2022 Guidelines for PAD

Canadian Cardiovascular Society 2022 Guidelines for Peripheral Arterial Disease

Beth L. Abramson, MD (Co-Chair), Mohammed Al-Omran, MD (Co-Chair), Sonia S. Anand, MD (Co-Chair), Zaina Albalawi, MD, Thais Coutinho, MD, Charles de Mestral, MDCM, PhD, Luc Dubois, MD, Heather L. Gill, MD, Elisa Greco, MD, Randolph Guzman, MD, Christine Herman, MD, Mohamad A. Hussain, MD, PhD, Victor F. Huckell, MD, Prasad Jetty, MD, Eric Kaplovitch, MD, Erin Karlstedt, MD, Ahmed Kayssi, MD, Thomas Lindsay, MDCM, G.B John Mancini, MD, Graham McClure, MD, M. Sean McMurtry, MD, PhD, Hassan Mir, MD, Sudhir Nagpal, MD, Patrice Nault, MD, Thang Nguyen, MD, Paul Petrsek, MD, Luke Rannelli, MD, Derek J. Roberts, MD, PhD, Andre Roussin, MD, Jacqueline Saw, MD, Kajenny Srivaratharajah, MD, James Stone, MD, PhD, David Szalay, MD, Darryl Wan, MD, Heather Cox, MD, Subodh Verma, MD, Sean Virani, MD

Canadian Journal of Cardiology
Volume 38 Issue 5 Pages 560-587 (May 2022)
DOI: 10.1016/j.cjca.2022.02.029

Over the past 2 decades there have been substantial advances in diagnostics, pharmacotherapy, and interventions to aid in the management of PAD patients

To summarize the evidence regarding approaches to diagnosis, risk stratification, medical and intervention treatments for patients with PAD, guided by the GRADE framework, evidence was synthesized, and assessed for quality

Fifty-six recommendations were made



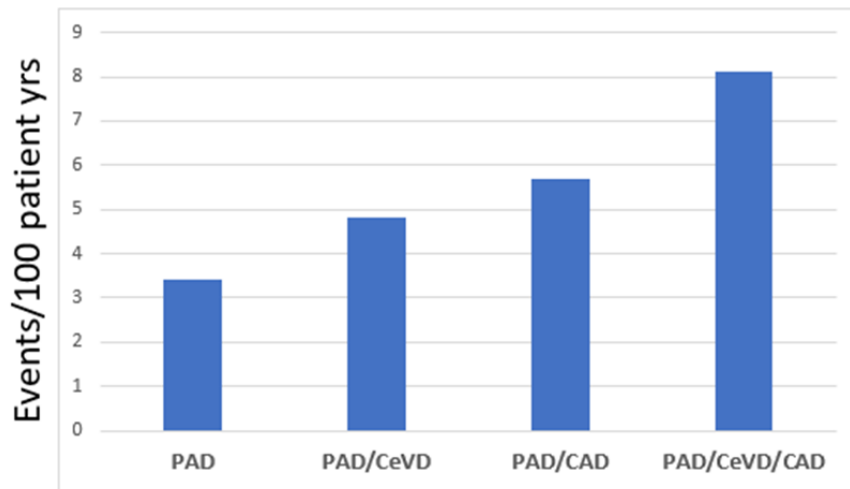
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The presence of polyvascular disease is the most potent risk factor for future cardiovascular events



Risk of cardiovascular event (cardiovascular death/MI/stroke) in patients with disease in multiple vascular beds
(Taken from secondary data analysis of EUCLID trial)

PAD = peripheral arterial disease; CeVD = cerebrovascular disease; CAD = coronary artery disease



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Lipid-lowering and PAD

We recommend that patients with PAD qualify as statin-indicated patients and should receive lipid-modifying therapy for the reduction of death, CV death, nonfatal MI, nonfatal stroke (MACE), and MALE concordant with the recommendations in the 2021 Canadian Cardiovascular Society (CCS) guidelines for the management of dyslipidemia (*Strong Recommendation; High-Quality Evidence*).

- a. Maximally tolerated dose of statin therapy
- b. Statin add-on therapies (ezetimibe and/or PCSK-9 inhibitors) if receiving maximally tolerated dose of statin therapy and the low-density lipoprotein cholesterol is 1.8 mmol/L, non-high-density lipoprotein cholesterol 2.4 mmol/L or apolipoprotein B100 0.7 mg/dL.

We recommend that patients with PAD, who, despite maximally tolerated dose of statin therapy have a **triglyceride level of 1.5-5.6 mmol/L**, should be considered for use of icosapent ethyl for the reduction CV death, nonfatal MI, and nonfatal stroke concordant with the recommendations in the 2021 CCS guidelines for the management of dyslipidemia (*Strong Recommendation; Moderate-Quality Evidence*).



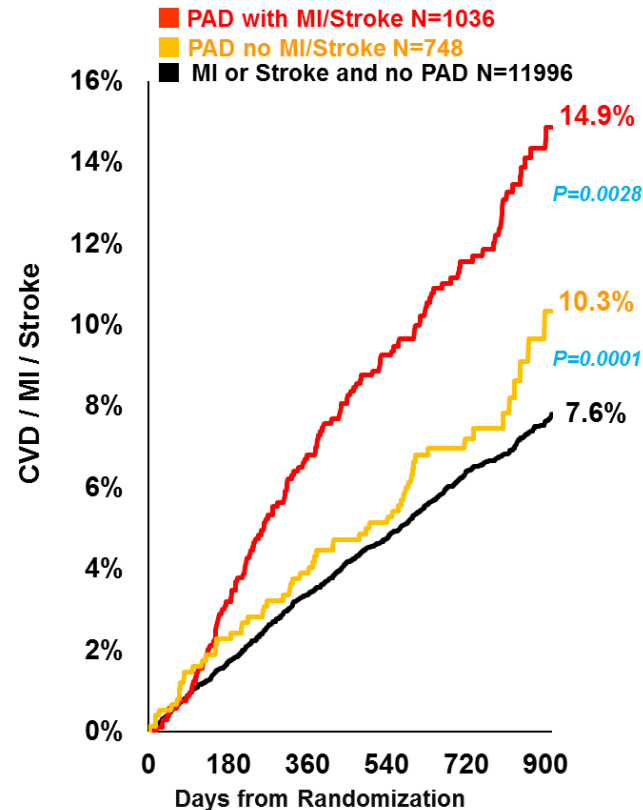
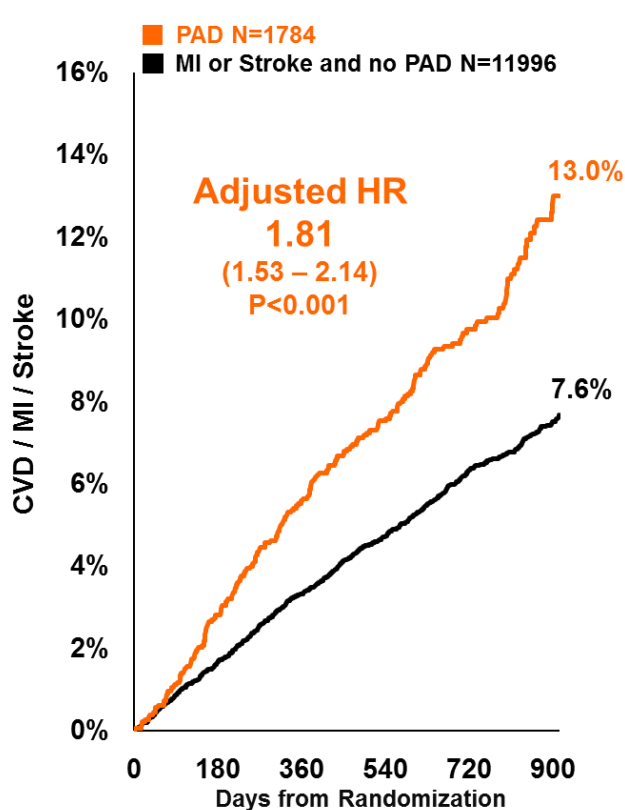
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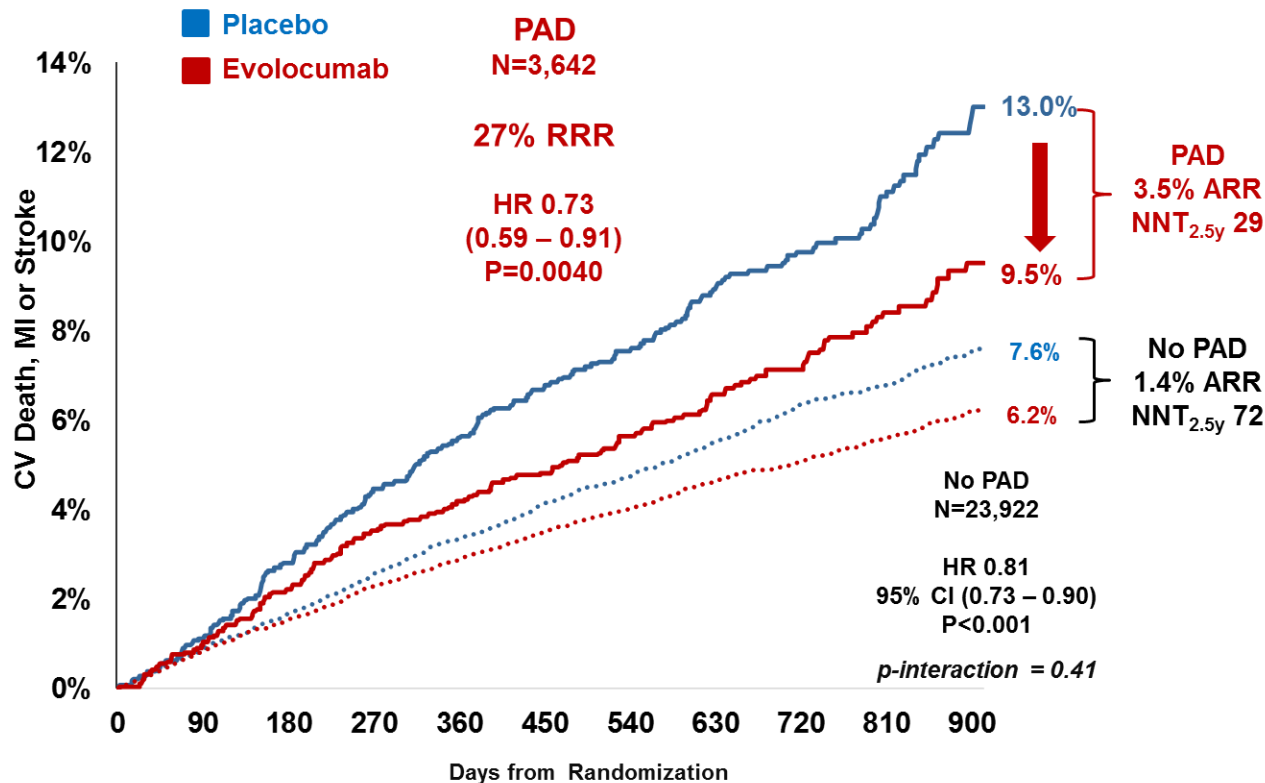
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Peripheral Artery Disease and Risk in Placebo Patients

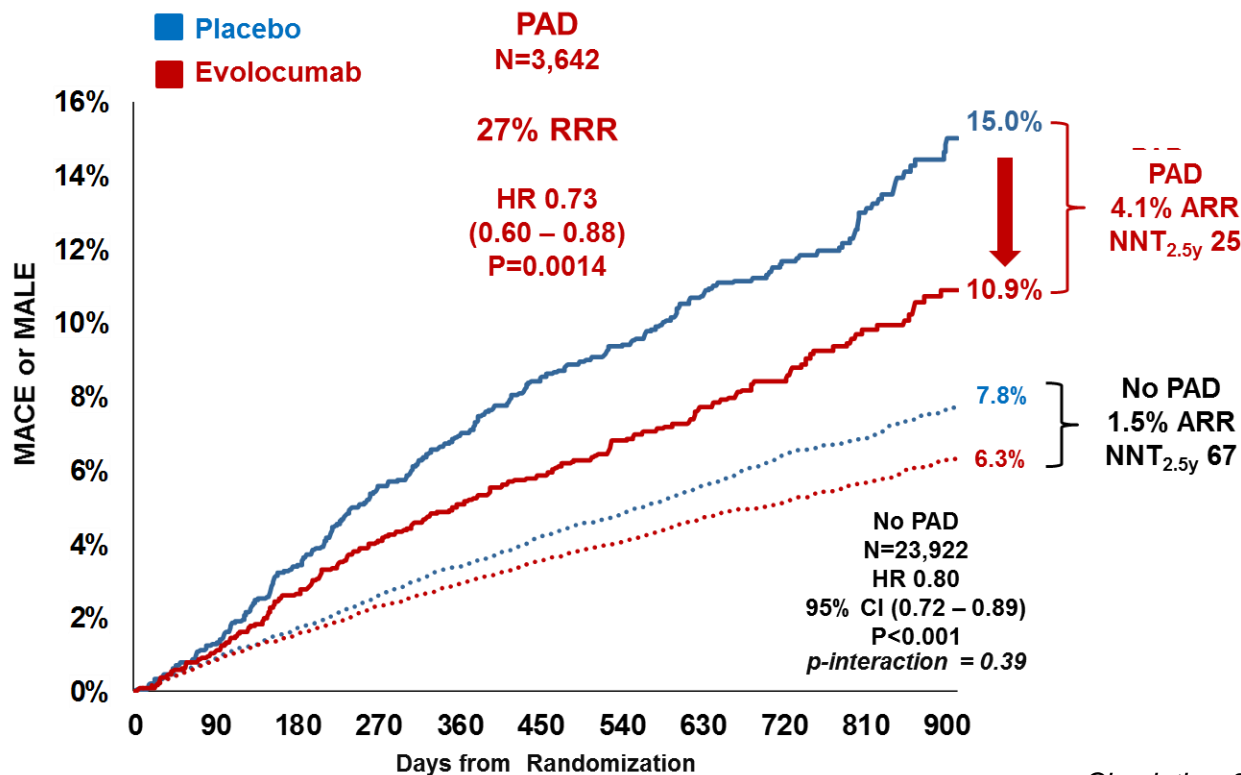


CV Death, MI or Stroke in Patients with and without Peripheral Artery Disease



MACE or MALE

In Patients with and without PAD



Summary



- **Patients with PAD are at heightened risk of MACE and MALE**
- **LDL-C lowering with evolocumab in patients with PAD:**
 - Reduces major adverse CV events with robust ARR
 - Reduces major adverse limb events
- **Benefits extend to PAD without prior MI or stroke with an ARR for MACE or MALE of 6.3% (NNT 16) at 2.5 years**



ASA in PRIMARY PREVENTION



Gaziano et al. *Lancet*. 2018 Aug. [//doi.org/10.1016/S0140-6736\(18\)31924-X](https://doi.org/10.1016/S0140-6736(18)31924-X)

McNeil JJ, et al. *NEJM*. 2018;379(16):1509-1518.

Zheng SL, et al. *JAMA*. 2019;321(3):277-287.

ACC/AHA CLINICAL PRACTICE GUIDELINE

2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

4.6. Aspirin Use

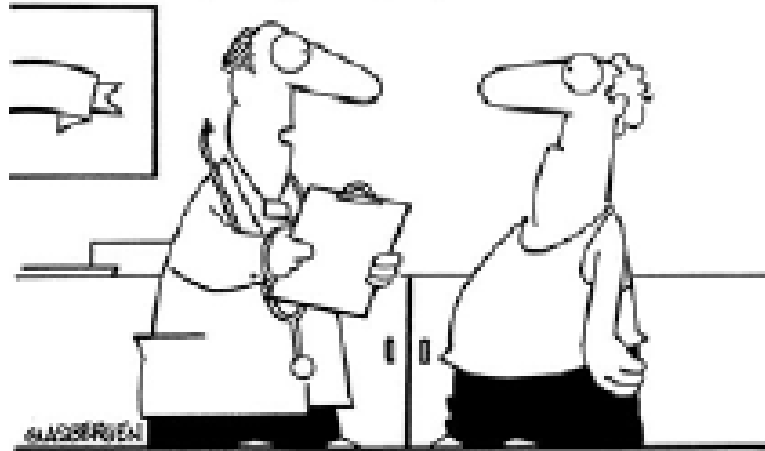
Recommendations for Aspirin Use		
Referenced studies that support recommendations are summarized in Online Data Supplements 17 and 18 .		
COR	LOE	Recommendations
IIb	A	1. Low-dose aspirin (75-100 mg orally daily) might be considered for the primary prevention of ASCVD among select adults 40 to 70 years of age who are at higher ASCVD risk but not at increased bleeding risk. ^{54,6-1-54,6-8}
III: Harm	B-R	2. Low-dose aspirin (75-100 mg orally daily) should not be administered on a routine basis for the primary prevention of ASCVD among adults >70 years of age. ^{54,6-9}
III: Harm	C-LD	3. Low-dose aspirin (75-100 mg orally daily) should not be administered for the primary prevention of ASCVD among adults of any age who are at increased risk of bleeding. ^{54,6-10}



Aspirin for Primary Prevention of CVD



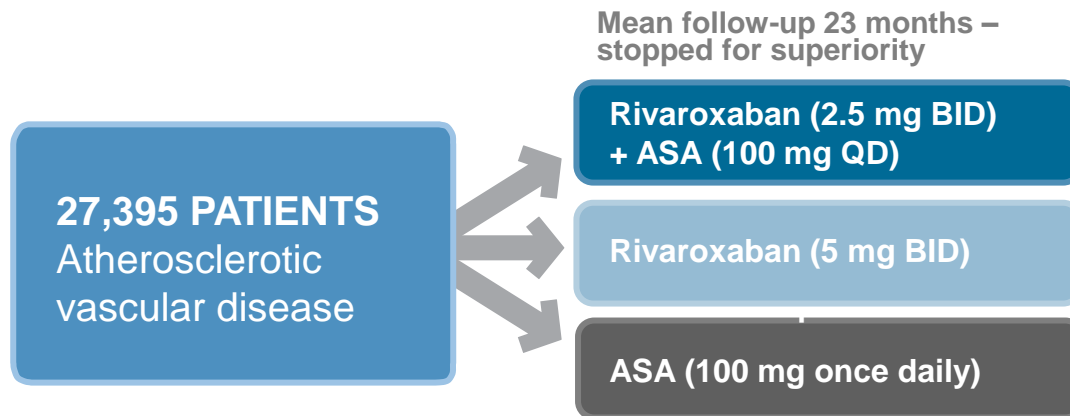
Copyright 2004 by Dandy Glasbergen, www.glasbergen.com



An Asprin a day will help prevent a heart attack if you have it for lunch instead of a cheeseburger

COMPASS TRIAL: STUDY DESIGN

Assessing DOAC* in stable CAD



Primary efficacy outcome: Composite of cardiovascular death, stroke or MI

Primary safety outcome: Modified ISTH major bleeding

*In this program, the term DOAC (direct oral anticoagulant) is used, recognizing that it is interchangeable with the term NOAC (non-vitamin K oral anticoagulant)
ASA, acetylsalicylic acid; BID, twice daily; CAD, coronary artery disease; DOAC, direct oral anticoagulant; ISTH, International Society on Thrombosis and Haemostasis; MI, myocardial infarction; NOAC, non-vitamin K oral anticoagulant; QD, once daily
Eikelboom JW *et al.* *N Engl J Med* 2017; 377:1319-30.

STUDY DETAILS

PRIMARY EFFICACY ENDPOINTS

Composite of MI, stroke or cardiovascular death

KEY INCLUSION CRITERIA

- Meet criteria for CAD or PAD
- Patients with CAD must also meet at least one of the following:
 - Age ≥ 65 years OR
 - Age < 65 years plus atherosclerosis in ≥ 2 vascular beds or ≥ 2 additional risk factors
- Criteria for CAD:
 - Previous MI
 - History of angina
 - PCI
 - CABG
- Criteria for PAD:
 - Claudication with objective evidence of arterial disease
 - Previous amputation or revascularization
 - Previous carotid revascularization
 - Asymptomatic carotid disease with $> 50\%$ stenosis

PRIMARY SAFETY ENDPOINTS

Modified ISTH major bleeding*

KEY EXCLUSION CRITERIA

- High risk of bleeding
- Stroke ≤ 1 month or any hemorrhagic or lacunar stroke
- Severe HF with known ejection fraction $< 30\%$ or NYHA class III or IV symptoms
- eGFR < 15 mL/min
- Concomitant use of other anticoagulants
- Chronic treatment with non-ASA antiplatelet therapy

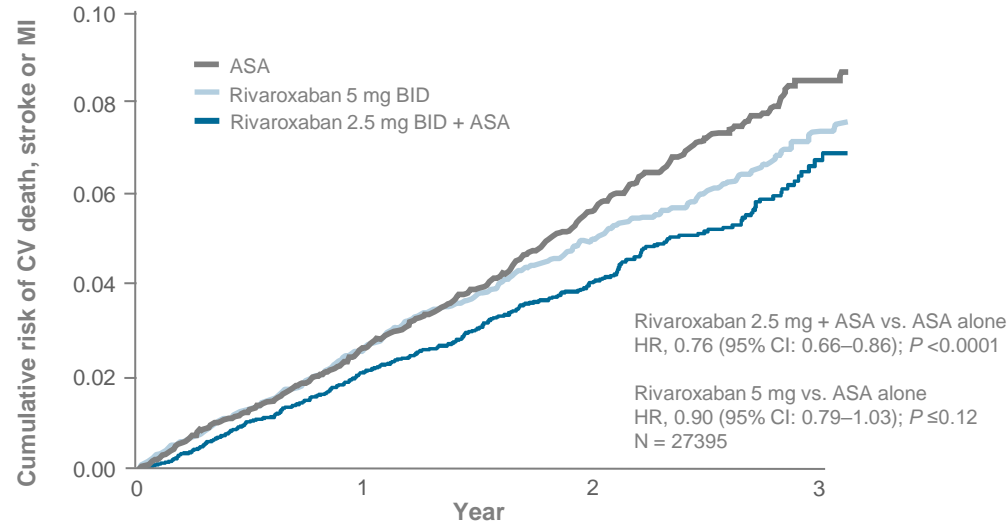
*Primary safety outcome is a composite of:

- Fatal bleeding and/or
- Symptomatic bleeding in a critical area or organ, such as intracranial, intraspinal, intraocular, retroperitoneal, intraarticular or pericardial, or intramuscular with compartment syndrome, or bleeding into the surgical site.

CABG: coronary artery bypass grafting; CAD: coronary artery disease; eGFR: estimated glomerular filtration rate; HF: heart failure; ISTH: International Society on Thrombosis and Haemostasis; MI: myocardial infarction; NYHA: New York Heart Association; PAD: peripheral artery disease; PCI: percutaneous coronary intervention.
Bosch, J., et al. Accepted for publication in *Can J Cardiol* (2017).

COMPASS TRIAL: CV DEATH, STROKE, MI

Primary endpoint in the entire study population

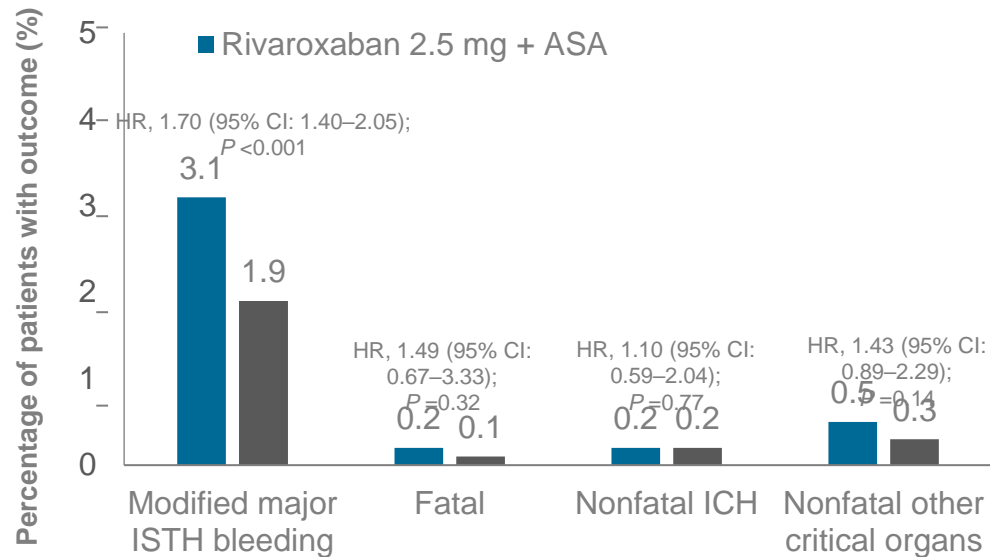


Vascular dose rivaroxaban 2.5 mg BID + ASA significantly reduced composite primary endpoint of CV death, stroke or MI vs. ASA alone in patients with stable atherosclerotic vascular disease

LU code 539

ASA, acetylsalicylic acid; BID, twice daily; CI, confidence interval; CV, cardiovascular; HR, hazard ratio; MI, myocardial infarction
Eikelboom JW *et al.* *N Engl J Med* 2017; 377:1319-30.

COMPASS TRIAL: MAJOR BLEEDING RATES



Antithrombotic therapy

We recommend treatment with **rivaroxaban 2.5 mg twice daily in combination with aspirin (80-100 mg daily)** for management of patients with **symptomatic lower extremity PAD who are at high risk for ischemic events** (high-risk comorbidities such as polyvascular disease, diabetes, history of heart failure, or renal insufficiency and/or high-risk limb presentation post peripheral revascularization, limb amputation, rest pain, ischemic ulcers) and at low bleeding risk

(Strong Recommendation; High-Quality Evidence).

LU 539 in Ont.



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Antithrombotic therapy (cont'd)

We recommend combination treatment with rivaroxaban 2.5 mg twice daily and aspirin or single antiplatelet therapy for patients **with symptomatic lower extremity PAD and low bleeding risk in the absence of high-risk limb presentation or high-risk comorbidities** (*Strong Recommendation; High-Quality Evidence*).

We recommend **single antiplatelet therapy** with either aspirin (75-325 mg) or clopidogrel (75 mg) be considered for patients with symptomatic lower extremity PAD at **high bleeding risk** who remain eligible for antithrombotic therapy (*Strong Recommendation; High-Quality Evidence*).



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SAVELIMB



PERIPHERAL ARTERIAL DISEASE

(PAD) is common, debilitating, and can be deadly.
Fortunately it's preventable when you think about it!

Think **SAVELIMB** with your at-risk patients

- S** Screen people at risk: smoking, diabetes, cardiovascular risk factors, age > 50
- A** Assess and ask about arterial diseases: ABI, AAA, and ask history of intermittent claudication
- V** Vascular studies: perform when indicated; such as ABI and arterial duplex scan
- E** Etiology: consider athero-thrombosis, embolism, and AF
- L** Lifestyle behaviour changes: reinforce exercise, smoking cessation, BP and cholesterol lowering, and diabetes management
- I** Intermittent claudication: ask about quality-of-life (e.g. pain with walking), and document distance
- M** Medication to treat: prescribe antiplatelets, antithrombotics, statins, ACE inhibitor, and check medication(s) for BP, cholesterol and diabetes
- B** Bypass surgery/revascularization procedures: think about when they are needed

SAVELIMBs and Lives.

#SAVELIMBSANDLIVES

AAA, abdominal aortic aneurysm; ABI, Ankle-Brachial Index; ACE, Angiotensin converting enzyme; AF, atrial fibrillation; ASCVD, atherosclerotic cardiovascular disease; BP, blood pressure

Peripheral Arterial Disease

Does your patient have risk factors?

Age >50
Diabetes
Smoking

Does your patient have symptoms of intermittent claudication and/or chronic limb-threatening ischemia?

If PAD is confirmed by objective testing (ABI or ultrasound); initiate treatments to reduce CV events and save limbs. Contact additional medical specialist with any questions on treatment or for referral.

When should you refer to a vascular surgeon?
Intermittent claudication
Rest pain
Blue or black toes
Ulcer

Preventing CV Events

- Behaviour: smoking cessation/exercise
- Antiplatelet or low dose rivaroxaban and aspirin
- Cholesterol lowering: statins/PCSK-9 inhibitors
- BP lowering: ACE inhibitors/ARB
- Diabetes management

Reducing Leg Symptoms +/- MALE

- Smoking cessation/exercise
- Low dose rivaroxaban and aspirin
- Statins/PCSK-9 inhibitors
- Revascularization procedures (endovascular and/or open surgical procedures)

ABI, Ankle-Brachial Index; ACE, Angiotensin converting enzyme; ARB, angiotensin receptor blockers; BP, blood pressure; CV, cardiovascular; MALE, major adverse limb events; PAD, peripheral arterial disease; PCSK-9, proprotein convertase subtilisin/kexin-9

SAVELIMBs and Lives.

#SAVELIMBSANDLIVES

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Polling Question 1:

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- EC ASA 81
- DAPT
- EC ASA 81 + Rivaroxiban 2.5 BID
- EC ASA 81 + Rivaroxiban 5 BID
- None of the above



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Leadership. Knowledge. Community.

Société
canadienne
de cardiologie

Communauté. Connaissances. Leadership.

Polling Question 2:

- In a 49 year old with PAD optimal anticoagulation is:
- EC ASA 81
- DAPT
- EC ASA 81 + Rivaroxiban 2.5 BID
- EC ASA 81 + Rivaroxiban 5 BID
- None of the above



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